REMARKS

Claim Rejections 35 U.S.C. §112

Claim 81 was rejected under 35 U.S.C. §112, ¶ 2, as being indefinite. Claim 81 has been amended for clarification. As such, reconsideration of the rejection is requested.

Claim Rejections 35 USC §101

Claim 70 was rejected under 35 U.S.C. § 101 because claim 70 appeared to positively claim the device in combination with the first blood vessel. Additionally, claims 71, 73, and 81 were also rejected because the blood vessel appeared to be part of the invention. Claims 70, 71, 73 and 81 have been amended to overcome these rejections. Reconsideration is requested.

Claim Rejections 35 USC §102

Claims 65, 66 and 69

Claims 65, 66 and 69 were rejected under 35 USC §102(b) as being anticipated by White.

Amended claim 65 calls for... a ring comprising windings formed of a strand of resilient wire, said windings connected together in a bundle to be closely associated, the windings wrapped one over the other and one around the other, and when undeformed the diameter of said bundle of windings corresponds with the diameter of said ring, the undeformed diameter of said ring greater than the first diameter of the tubular graft, said ring secured to said graft adjacent one of said free ends.

White does not clearly show the structure of claim 65. For example, White's wire 17 has a closed sinusoidal shape with two ends that are twisted together to form a tail 18. White's tail 18 extends longitudinally along the outside surface of a crimped tube 16. Page 9, line 34-page 10, line 1. In contrast, the wire 17 is spaced about the circumference of a graft. Page 10, lines 5-8; Figure 6. Thus, the diameter of White's twisted tail 18 does not correspond with the diameter of the wire 17. Also, the twisted tail 18 does not

have windings that are wrapped one over the other and one around the other. Thus, for this additional reason, claim 65 is distinguished over White.

Amended claim 66 calls for ...an annular element comprising a bundle of radially overlapping windings formed of a single strand of resilient wire, the windings connected together, the diameter of the bundle of windings corresponding with the diameter of the annular element, the windings adapted to be concentric with a tubular graft....

White fails to disclose such a structure. For example, as explained above White's twisted ends 18 does not have a diameter that corresponds with the diameter of the annular element 17. *See* Figure 6. Also, the twisted ends 18 extends longitudinally along the crimped tube 16. *Id.* Thus, the center of the twisted ends 18 and the center of the tube 16 are parallel. For at least these reasons, White fails to disclose the structure of claim 66.

Advantageously, the annular element or ring of some embodiments of the present invention is flexible, including flexibility in the bending direction. As a result of flexibility and/or resiliency the annular element or ring may spring open of its own accord when placed in a desired location within a body passage. The flexibility of the annulus allows firm attachment to the inside of an irregular aorta, which may lower the risk of prosthesis migration. Also, the flexibility of the annulus allows a soft fit, without harm to the inside wall of a blood vessel. The easy and free deformation of the annular element or ring allows it to follow the heartbeat of the person in which the ring/element is situated. And, in embodiments where the annulus is deformed into a C-shape, the openings of the renal arteries are not occluded when the annulus is disposed in the abdominal aorta.

In contrast, White's wire is malleable, but not substantially resilient. Page 9, lines 23-28. That is, the wire 17 of White does not expand to contact a body passage due to its own resiliency; it has to be physically expanded to contact passage. *Id.* As such, embodiments of the present invention have advantages over White, and as will become clear from the explanations below, the other art cited in the Office action as well.

Claims 65-68

Claims 65-68 were rejected under 35 USC §102(e) as being anticipated by Dereume.

Dereume's tubular support 22 does not anticipate claim 65. For example, the elements of Dereume's tubular support 22 are braided in an open braid. In contrast, the windings of claim 65 are connected together in a bundle to be closely associated and the windings are wrapped one over the other and one around the other. As such, amended claim 65 is distinguished over Dereume. Reconsideration of the rejection is requested.

Under a similar analysis, claim 67 is distinguished over Dereume.

Claim 66 calls for ...an annular element comprising a bundle of radially overlapping windings formed of a single strand of resilient wire.... Dereume's tubular support 22 has braided wire *elements*. Column 4, lines 49-58 (emphasis added). Typically, to braid something more than one strand is needed. Also, Dereume describes the elements in plural form. Thus, Dereume uses more than a single wire to form his tubular support 22. Because Dereume fails to disclose a single wire that is radially overlapping, Dereume does not anticipate claim 66. Reconsideration of the rejection is requested.

Claim 67

Claim 67 was rejected under 35 USC §102(e) as being anticipated by Carpenter. As was previously explained, Carpenter fails to disclose a wire. *See* Response to Paper No. 37. *See also* Appeal No. 2001-1407, p. 6. Thus, Carpenter does not anticipate claim 67.

Claims 70-79 and 81

Claims 70-79 and 81 were rejected under 35 USC §102(b) as being anticipated by Inoue ('305).

Claim 70 calls for... an element folded along a diametric axis into a C-shaped configuration.... Claim 75 calls for ... an element foldable along a diametric axis into a C-shaped configuration overall... with an arcuate portion of the C-shaped element

engaged with a blood vessel. The examiner asserts that Inoue's graft is "*capable of* being used in a vessel where the C-shaped bends remain therein." Office action, page 3 (emphasis added). But, merely being capable of something is not the standard to anticipate. Rather, to anticipate under §102(b) the prior art reference must either expressly disclose or inherently describe every element as set forth in the claim; the identical invention must be shown in as complete detail as is contained in the claim.

The examiner does not assert that Inoue expressly discloses the claimed prosthesis. Likewise, Inoue does not inherently describe the claimed prosthesis. To be inherent, the reference must necessarily include the missing descriptive matter. Mere possibilities or a characteristic that might be present in the prior art reference do not inherent features make. Also, it is the examiner's burden to provide a basis in fact and/or technical reasoning to support his determination that the alleged inherent characteristic is necessarily present. Because the examiner asserts a "capability" and not a feature that is necessarily found in Inoue, it is submitted that Inoue does not anticipate independent claim 70 or claims dependent thereon.

The examiner's reliance on Figures 12, 13, 17C, 18C and 23 of Inoue is to no avail. For a drawing to anticipate claims it must show the entire claimed structure and how it is put together. Claims 70, 75, and 81 directed toward prosthesis as positioned within a blood vessel. In particular, after placement in the desired location, an annular, resilient element of the prosthesis has a fold along a diametric axis, which results in a C-shaped configuration in some embodiments. With a C-shape configuration, the graft of the prosthesis can be located distal to a point of intersection of blood vessels such as the abdominal aorta and the right and left renal arteries. As shown in Figures 4 and 5 of the present application this configuration prevents the graft from occluding the openings of the renal arteries. For example, the loops 38 of the ring 30 may extend past the left and right renal arteries when the ring is within the abdominal aorta, very close to the renal arteries. But, blood is allowed to flow freely. Thus, in this instance, the prosthesis allows treatment of the whole diseased part, even that which is located very close to the

openings to intersecting blood vessels. Also, the ring of the present invention can follow the heartbeat of the person due to its free deformation.

In contrast, none of the figures of Inoue that the examiner relies upon show an annular element folded into a C-shaped after being positioned in a blood vessel. For example, in Figures 12 and 13 respectively, the front ring 10 is folded inside of a catheter and is slightly folded while being released. Column 3, lines 52-57. But, as shown in Figure 14B, once the artificial blood vessel 7 of Inoue is fully released, it is "restored to its original tubular contour by the resiliency of the end wire rings 10...and urged against the inner wall of the blood vessel 9." Column 9, lines 9-12. Notably, the diameter of the end wire rings 10 is "set in accordance" with that of the artificial blood vessel 7. Column 5, lines 58-62. That is, as indicated in the drawings of Inoue, the artificial blood vessel 7 and the end wire rings 10 appear to have the same or about the same diameter. There is nothing in Inoue to suggest that the end wire rings 10 are sized to be greater than the diameter of the blood vessel in which the artificial blood vessel 7 is to be placed. For example, as shown in Figure 15 of Inoue, a balloon is inflated "...to expand the artificial blood vessel 7 *completely* and securely fit it onto the inner wall of the blood vessel 9." Column 9, lines 17-27 (emphasis added). Thus, after expansion, the rings 10 are also completely restored to be circular, without bend. This understanding is supported by Inoue's description of an embodiment where folded rings 10 are restored "to their original shape", which is circular. *See* column 9, lines 46-58. Taken together, it is clear that Inoue does not specifically disclose or suggest prosthesis including an annular resilient element, folded along a diametric axis into a C-shaped configuration, after placement in a blood vessel.

Simply folding a ring for insertion where the ring does not remain deformed after placement does not meet the language of claim 70. *See* Figures 12, 13, 17C, and 18C. In particular, the examiner has failed to show how Inoue's device "is capable of" being positioned past a point of intersection of two different blood vessels so as not to occlude the opening and permit communication. The simple fact is the Inoue device does not have this capability. Also, merely placing the ring 10 on the outside of the cloth rather

than inside does not alter the fact that Inoue does not contemplate a ring that remains deformed once positioned within a blood vessel or body part. In each drawing of Inoue where the artificial blood vessel 7 is positioned in a body passage, the rings 10 are fully expanded to their original circular shape. *See* Figures 14B, 15, 31, and 32. Thus, the rings 10, especially in combination with the remainder of the frame 32, are designed for complete expansion while positioned in the body. *See* Figures 14B, 15, 31 and 32. As such, the figures of Inoue do not show the entire claimed structure; Inoue does not anticipate claim 70.

Under a similar analysis, Inoue does not anticipate independent claims 75 and 81, and claims dependent thereon. In particular, the examiner has not shown where Inoue expressly or inherently discloses an arcuate portion of a C-shaped element that is engaged with a blood vessel or where only part of a graft and part of an annular element contacts a portion of a first blood vessel that is located past a second blood vessel where the first and second blood vessels intersect.

CONCLUSION

Support for Amendments to the Claims

The amendments to the claims are supported in specification and the drawings. In particular, the examiner is referred to Figures 1-5, 8-10, 17-21, and 23, and corresponding text. The cited figures and text are intended to show where support for amendments may be found without reading limitations into the claims.

Copending Applications

Per the examiner's request, a list of the co-pending applications is provided below. As examiner Prebilic is the examiner for all three applications listed below, current claims have not been included herewith. The examiner is requested to refer to each application's file for a copy of the claims.

1. Serial No. 10/118,409, filed April 8, 2002, which is a continuation of the present application (08/878,908).

2. Serial No. 10/124,994, filed April 18, 2002, which is a divisional of the present application.

3. Serial No. 10/832,159, filed April 26, 2004, which is a divisional of application 09/365,860, which issued as Patent No. 6,740,111; which is a continuation of the present application.

In view of the amendments and remarks herein, the application is in condition for allowance. The commissioner is authorized to charge any additional fees, including extension of time fees, or credit any overpayment to Deposit Account No. 20-1504 (VAS.0002US).

Respectfully submitted,

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